

### **REMARKS/ARGUMENTS**

Claims 11 and 34-44 are pending in this application. Claims 1-10 and 12-33 had been previously canceled. In the specification, paragraphs [0002], [00003], [0046], [0075], [0103], [0104], [0110], [0111], [0112], [0113], [0122], [0123], [0125], [0126], [0129], [0135], [0159], [0160], [0162], [0164], [0169], and [0171] and the Abstract have been amended in response to the Office's objection to correct informalities. Claims 35 and 36 have also been amended in response to the Office's objection, replacing "hyperplasic" with the correct spelling, "hyperplastic."

#### **35 U.S.C. §103 Rejections**

Claims 11 and 34-44 were finally rejected pursuant to 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. 2001/0043930 A1, and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3):200-204, February 1964) and U.S. Pat. 6,312,708 as evidence by Vakil et al. (C.M.A. Journal 109:29-32, July 7, 1973).

#### **I. Introduction**

One rejection remains in this application and is currently being presented for review. Claims 11 and 34-44 were finally rejected as being unpatentable over U.S. Patent Application Publication No. 2001/0043930A1 ("Aoki"), in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) ("Wald") and U.S. Patent No. 6,312,708 ("Donovan"), as evidenced by Vakil et al. (C.M.A. Journal 109: 29-32, July 7, 1973) ("Vakil").

The Office concludes that it would have been obvious to one skilled in the art "to implement a potential method for successful treatment of apocrine gland carcinoma of the breast, which excretes a secretion with botulinum toxin A with modifications as

suggested by Aoki.” (Final Office Action, 4.) Applicants respectfully disagree with the aforementioned rejection for the following reasons.

**II. 35 U.S.C. § 103(a) Rejection of Claims 11 and 34-44 Should Be Reversed Because the Office Has Not Met Its Burden of Establishing a *Prima Facie* Case of Obviousness.**

Obviousness is a question of law based on underlying factual inquiries. MPEP § 2141(II). Support for any 35 U.S.C. § 103 rejection must include a “clear articulation of the reason(s) why the claimed inventions would have been obvious” to one of ordinary skill in the art at the time the inventions were made. MPEP § 2142, *citing KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The Office bears the initial burden of factually supporting a *prima facie* conclusion of obviousness, and if the Office does not meet this burden, the Applicants are “under no obligation to submit evidence of nonobviousness.” MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Here, the Office has failed to provide factual evidence or clearly articulated reasons explaining why the claimed inventions would have been obvious to a person of ordinary skill at the time of the invention. Thus, Applicants submit that without conceding to the propriety of the asserted combination, the combination of Wald and Aoki, in view of the knowledge of one ordinarily skilled in the art, is insufficient to present *prima facie* obviousness. As such, Applicants respectfully request the Office withdraw this rejection.

**A. Rejection of Independent Claim 11.**

The Office has rejected independent claim 11 of the present application pursuant to 35 U.S.C. § 103(a) for the reasons set forth *supra*. The Office asserts that Aoki teaches “the local administration of botulinum toxin type A to a patient suffering from a disease or conditions such as excessive sweating, lacrimation and mucus secretions” (June 13, 2008 Office Action, 6 (“Non-Final Office Action”)); that Wald teaches apocrine gland carcinoma of the breast, “which releases a substance” (Non-Final Office Action,

6); that Donovan teaches “a biodegradable polymer implant capable of releasing botulinum toxin A” and botulinum toxin injections of about 0.01 U/kg to about 35 U/kg (Non-Final Office Action, 6); and that Vakil teaches that “mammary and certain axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar” (Non-Final Office Action, 4).

1. The Proposed Combination of References Does Not Teach or Suggest All the Claim Limitations.

To establish *prima facie* obviousness of a claimed invention, the Office must show that “**each and every claim feature**” is taught or suggested in the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974) (emphasis added). Contrary to the Office’s contention, the Office has failed to show that each and every feature recited in independent claim 11 is taught or otherwise suggested in the combined teachings of Aoki, Wald, Donovan and Vakil. (See Final Office Action, 5). The proposed combination of references does not teach or suggest (1) a method for treating a mammary gland disorder comprising the local administration of about  $10^{-2}$  U/kg to about 200 U/kg of botulinum toxin type A to a patient’s mammary gland, or (2) the application of botulinum toxin to a mammary gland disorder treats or causes the regression or remission of atypical tissue, thereby treating the disorder. As such, the proposed combination fails to teach each and every limitation presently claimed.

Aoki teaches, *inter alia*, methods of treating cholinergic-controlled secretions such as excessive sweating, lacrimation and mucus secretions with botulinum toxin. (Aoki, [0014]). It is well known in the art that mucus secretions as taught in Aoki are viscous mixtures comprised of mucin and are secreted into body cavities. A hypothetical person of ordinary skill in the art at the time of the present invention would not have related Wald’s description of a “definite substance” that elaborates from apocrine glands with the mucus secretions taught in Aoki.

Wald teaches a “rare” disease called apocrine gland carcinoma of the breast. (Wald, 201, col. 1). Wald explains that these carcinomata can be cystic or solid, and consist of columnar eosinophilic cells found on the apocrine gland ducts of the breast. (Wald, 201, col. 2). The Office erroneously concludes that Wald teaches an apocrine gland carcinoma of the breast from which a “substance” is released, and erroneously equates this “substance” to the mucus secretions described in Aoki. (See Non-Final Office Action, 6). However, as described in Wald’s case report, apocrine gland carcinoma is **not** associated with a discharge. (Wald, 200, col. 1). The “substance” the Office refers to is a substance that is generally known to exude from apocrine glands. (Non-Final Office Action, 6). This substance is not related to or taught in reference to the apocrine gland **carcinoma**.

Vakil teaches that “mammary and certain axillary sweat glands are histologically of the apocrine type, and their secretions are biochemically similar.” (Vakil, 109, col. 2). The Office concludes that Vakil supports Wald’s teachings that “tissues of the breast are known to emit secretions.” (March 4, 2009 Office Action, 5 (“Final Office Action”)). However, Vakil, similar to Wald, does not teach or suggest the treatment of a mammary gland disorder or secretions from atypical tissue in mammary glands.

Donovan teaches specific botulinum toxin type A dosages appropriate for implantation and thus, does not cure the aforementioned deficiencies. (See Donovan, col. 25-26).

The combined referenced, as suggested by the Office, do not teach or suggest a method for treating a mammary gland disorder by locally administering a specific amount of botulinum toxin type A to the gland in order to treat or cause the regression or remission of atypical tissue. The combined references do not teach or suggest treatment methods for mammary gland disorders, the local administration of specific dosages of botulinum toxin to a mammary gland treating or causing regression or remission of atypical tissue, or reducing secretions from atypical tissue. Thus, the

Office has failed to show that each and every claim limitation is taught in the cited art and as such, has failed to adequately present a *prima facie* case of obviousness. See MPEP § 2143(A); *citing KSR*, 550 U.S.C. at 418-419.

2. Wald Teaches Away from the Present Claims.

To support its conclusions and its *prima facie* case of obviousness, the Office must clearly articulate a reason that would have prompted one ordinarily skilled in the relevant art to combine the elements the way the claimed invention does. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492, F.3d 1350, 1356-1357 (Fed. Cir. 2007). Here, the Office fails to provide a logical rationale explaining the suggestion or motivation that would have prompted such an artisan to combine the elements the way the claimed methods do. As a result, the Office has not met its *prima facie* burden of going forward.

As explained in detail *supra*, Wald teaches the diagnosis of a “rare” disease called apocrine gland carcinoma of the breast which is described as **not** being associated with a discharge. (Wald, 201, col. 1). Therefore, in actuality, Wald **teaches away** from the present claims. A reference is said to teach away if a person of ordinary skill, upon reading the reference, “would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 552 (Fed. Cir. 1994). In the present case, a skilled artisan, upon reading Wald, would be led to conclude that apocrine gland carcinoma is not associated with a discharge and would therefore, not seek to combine it with a reference teaching methods of treating cholinergic-controlled secretions (i.e. Aoki). Accordingly, such a hypothetical artisan would not have found a teaching, suggestion, motivation or desirability to combine and modify the cited art as suggested by the Office to reach the conclusions reached by the Office.

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions which would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. V. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

The teachings of Aoki and Wald, considered in their entirety, would not lead a person of ordinary skill in the art at the time to the presently claimed methods. The teachings of Donovan and Vakil do not remedy the defects in Aoki and Wald and thus, the combined references do not support *prima facie* obviousness.

3. The Office's Conclusion of Obviousness Is Based on Impermissible Hindsight.

To assert a claimed invention as obvious, the Office must identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the presently claimed methods do. See *KSR*, 550 U.S. at 401. Here, the Office avers that an artisan skilled the relevant art at the time of invention would have been motivated to treat mammary cancer with botulinum toxin A because Wald teaches apocrine gland carcinoma of the breast and Aoki teaches "treating various disorders with botulinum toxin type A and suggests modification can be made." (Final Office Action, 6). The Office fails to identify what explicit or implicit motivation, or general knowledge available to one ordinarily skilled in the art at the time of the invention would have led the artisan to combine or modify the cited references, as combined by the Office, to arrive at the present methods.

When attempting to create a *prima facie* case of obviousness, it is crucial for the Office to avoid impermissible hindsight and to base its conclusion solely on what would have been obvious to one of ordinary skill in the art at the time of the invention, without any knowledge of the invention. In *re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). Evidence of a suggestion, teaching or motivation to combine may flow from the prior references, the knowledge of the ordinary-skilled artisan and, in some cases, the nature of the problem to be solved. *Id.* The suggestion, teaching or motivation may not flow from the presently disclosed invention. See *In re Dow Chemical*, 837 F.2d 469, 473 (Fed. Cir. 1988). In other words, the Office's conclusion of *prima facie* obviousness must be expressly or impliedly based on the cited references or must be supported by a "convincing line of reasoning" as to **why** an artisan would have found it obvious "to pick

and choose” the combination of elements, ***without using Applicants’ claims as a reference***. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

It is impermissible for the Office to use the present claims “as an instruction manual or a template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260, 1264 (Fed. Cir. 1992). Here, the Office has done exactly that. The Office has used the present claims as a road map to piece together dissimilar, unrelated teachings in an effort to reconstruct the present invention. The test for obviousness is what the combined teachings would have suggested to an ordinary skilled artisan. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). The combined teachings of Wald and Aoki do not suggest a method for treating mammary gland cancer by administering botulinum toxin type A to a cancer cell. The Office has not identified a reason that would have prompted one of ordinary skill in the art to combine the elements as the claimed invention does and therefore, has not established a *prima facie* case of obviousness. See *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007). As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 34.

#### **B. Rejection of Dependent Claim 35.**

Claim 35 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 35. See 35 U.S.C. § 112.

Further, the references as combined do not teach the administration of botulinum toxin to treat hyperplastic or neoplastic mammary gland cells. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-

controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the treatment of hyperplastic or neoplastic mammary gland cells with botulinum toxin. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 35.

### **C. Rejection of Dependent Claim 36.**

Claim 36 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method claimed in claim 36. See 35 U.S.C. § 112.

Further, the references as combined do not teach the administration of botulinum toxin to reduce secretions from atypical tissues such as hyperplastic tissue, a cyst, or a neoplasm. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found



obvious the present claim relating to the administration of botulinum toxin to reduce secretions from atypical tissues such as hyperplastic tissue, a cyst, or a neoplasm. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 36.

**D. Rejection of Dependent Claim 37.**

Claim 37 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 37. See 35 U.S.C. § 112. As such, the Office has not presented a *prima facie* case of obviousness and Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 37.

**E. Rejection of Dependent Claim 38.**

Claim 38 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 38. See 35 U.S.C. § 112.

Further, the references as combined do not teach the direct injection of botulinum toxin into atypical tissue. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the direct injection of botulinum toxin into atypical tissue. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 38.

**F. Rejection of Dependent Claim 39.**

Claim 39 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method claimed in claim 39. See 35 U.S.C. § 112.

Further, the references as combined do not teach the implantation of botulinum toxin onto or into atypical tissue. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e.

Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the implantation of botulinum toxin onto or into atypical tissue. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 39.

**G. Rejection of Dependent Claim 40.**

Claim 40 is dependent on claim 11. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 11 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 40. See 35 U.S.C. § 112.

Further, the references as combined do not teach the administration of botulinum toxin to reduce the diameter of atypical tissue in the mammary gland by about 20% to about 100%. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the administration of botulinum toxin to reduce the diameter of atypical tissue in the mammary gland by about 20% to about 100%. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has

failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 40.

#### H. Rejection of Independent Claim 34.

The Office has rejected independent claim 34 of the present application pursuant to 35 U.S.C. § 103(a) for the reasons set forth *supra*. The Office asserts that Aoki teaches “the local administration of botulinum toxin type A to a patient suffering from a disease or conditions such as excessive seating, lacrimation and mucus secretions” (Non-Final Office Action, 6); that Wald teaches apocrine gland carcinoma of the breast or “breast tissue that is not typical or normal” (Final Office Action, 5) that “releases a substance” (Non-Final Office Action, 6); that Donovan teaches “a biodegradable polymer implant capable of releasing botulinum toxin A” and botulinum toxin injections of about 0.01 U/kg to about 35 U/kg (Non-Final Office Action, 6); and that Vakil teaches that “mammary and certain axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar” (Non-Final Office Action, 4).

However, contrary to the Office’s assertions, the cited references do not teach or suggest the presently claimed methods. To establish *prima facie* obviousness of a claimed invention, the Office must show that “**each and every claim feature**” is taught or suggested in the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974) (emphasis added). Here, Aoki teaches the use of botulinum toxin to treat certain cholinergic-controlled secretions such as excessive sweating and mucus secretions (Aoki, [0014]); Wald teaches the diagnosis of a “rare” disease called apocrine gland carcinoma of the breast (Wald, 201, col. 1); Donovan teaches specific dosage of botulinum toxin type A appropriate for implantation (Donovan, col. 25-26); and, Vakil teaches that an association between wet cerumen and rates of breast cancer in population groups can be made because “ceruminous, mammary and certain axillary sweat glands are

histologically of the apocrine type, and their secretions are biochemically similar” (Vakil, 109, col. 2).

The combined teachings of these cited references do not teach or suggest (1) a method for treating a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, and proliferative breast disease, or (2) local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of botulinum toxin type A to treat the aforementioned mammary gland disorders. In fact, the cited references do not teach or suggests methods of treating any type of mammary gland disorders with botulinum toxin type A. One of ordinary skill in the art at the time, presented with the cited references would not have found the present claim relating to the treatment of certain mammary disorders with botulinum toxin obvious.

This is particularly true since Wald teaches that apocrine gland carcinoma is **not** associated with a discharge. (Wald, 200, col. 1). Therefore, in actuality, Wald teaches away from the present claims. A reference is said to teach away if a person of ordinary skill, upon reading the reference, “would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 552 (Fed. Cir. 1994). In the present case, a skilled artisan, upon reading Wald, would be led to conclude that apocrine gland carcinoma is not associated with a discharge and would therefore, not seek to combine it with a reference teaching methods of treating cholinergic-controlled secretions. As such, the Office has not presented a *prima facie* case of obviousness and Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 34.

#### **I. Rejection of Dependent Claim 41.**

Claim 41 is dependent on claim 34. To avoid repetition, the arguments presented *supra* for claim 34 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 34 and “[a] claim in dependent form shall be construed to

incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 41. See 35 U.S.C. § 112. As such, the Office has not presented a *prima facie* case of obviousness and Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 41.

#### **J. Rejection of Dependent Claim 42.**

Claim 42 is dependent on claim 34. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 34 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 42. See 35 U.S.C. § 112.

Further, the references as combined do not teach the direct injection of botulinum toxin to a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the direct injection of botulinum toxin to a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As

such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 42.

**K. Rejection of Dependent Claim 43.**

Claim 43 is dependent on claim 34. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 34 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 43. See 35 U.S.C. § 112.

Further, the references as combined do not teach the implantation of botulinum toxin onto or into a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the implantation of botulinum toxin onto or into a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 43.

**L. Rejection of Dependent Claim 44.**

Claim 44 is dependent on claim 34. To avoid repetition, the arguments presented *supra* for claim 11 are incorporated herein by reference. Accordingly, since the combination of Aoki, Wald, Donovan and Vakil does not teach or suggest all the limitations set forth in claim 34 and “[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers,” it necessarily follows that the combined references do not disclose the method of claim 44. See 35 U.S.C. § 112.

Further, the references as combined do not teach the administration of botulinum toxin to reduce the diameter of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease by about 20% to about 100%. One of ordinary skill in the art at the time, presented with a reference teaching methods of treating cholinergic-controlled secretions such as sweating, lacrimation and mucus secretions with botulinum toxin (i.e. Aoki), a reference teaching apocrine gland carcinoma not associated with a discharge (i.e. Wald), a reference teaching associations between wet cerumen and breast cancer rates (i.e. Vakil), and a reference teaching implantation of botulinum toxin (i.e. Donovan) would not have found obvious the present claim relating to the administration of botulinum toxin to reduce the diameter of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, or proliferative breast disease by about 20% to about 100%. These limitations are not discussed in any of the cited references and thus, the cited references do not teach each and every presently claimed limitation and the Office has failed to satisfy its burden of presenting a *prima facie* case of obviousness. See *In re Royka*, 490 F.2d at 985. As such, Applicants respectfully request the Office withdraw the 35 U.S.C. § 103(a) rejection of claim 44.

### III. CONCLUSION

In summary, Applicants assert that the Office’s 35 U.S.C. § 103(a) obviousness rejection is improper because the Office has failed to meet its initial burden of



establishing a *prima facie* case of obviousness, as detailed above. Accordingly, Applicants ask the Office to withdraw the aforementioned rejection of claims 11 and 34-44. Applicants further ask the Office to issue a Notice of Allowance for all pending claims and to allow the application to proceed to issue.

Applicants file herewith a deposit account authorization for payment of the fee associated with the filing of this response. If any other fee is due, the Commissioner is authorized to charge any such fee to deposit account number 503207.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Dated: \_\_\_\_\_

\_\_\_\_\_  
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